DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed July 18, 2008 is acknowledged. Claims 1, 6-7, 9-13, 16-27, 45-46, 49-51 remain pending in this application.

Claim Rejections - 35 USC § 112

In view of Applicants Amendments to the claims, the rejection under 35 USC 112, 2nd paragraph has been withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6-7, 9-13, 16-19, 21-24, 26-27, 45, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dilantin Physician Information Sheet in view of Vandecruys et al. (US Patent 6,667,060).

The Dilantin information sheet discloses 100mg Extended Release Oral Capsules, used as an antiepileptic drug, comprising 100mg phenytoin sodium, lactose monohydrate, sugar, talc and magnesium stearate. The capsules are made of gelatin and titanium dioxide. The product in vivo performance is characterized by a slow and extended rate of absorption with a peak blood concentration expected in 4-12 hours

(see description). The product is supplied as hard, filled no. 3 capsules containing a white powder.

The Dilantin Information Sheet does not disclose a hydrophilic polymer is added to the phenytoin powder.

Vandecruys discloses a controlled release composition comprising hydrophilic controlled release matrix polymers (abstract). The hydrophilic polymers include hydroxypropylmethylcellulose, hydroxypropylcellulose, and tragacanth, agar, guar, xanthan, for example (column 9, lines 1-58).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of the Dilantin Information Sheet with the teachings of Vandecruys polymers in order to provide a controlled pharmacokinetic release profile for a preparation. Vandecruys further discloses that depending on the amount of polymers used, the release profile can be tuned (column 9, lines 55-59).

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It is noted that Applicant is claiming a composition; therefore, the recitation of "wherein the powder blend has been screened through a mesh after blending but before filling in the capsules" is considered a process step, resulting in a product by process

claim. The process step is therefore not given patentable weight when considering the product claim. It is further noted that it is the position of the examiner that it would have been obvious to a person of ordinary skill in the art to filter or pass the powder through a mesh prior to filling the capsules in order to obtain a uniform particle size for the powder.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Dilantin does not qualify as prior art, However, it is submitted by the Examiner that Applicant has already conceded that Dilantin is considered prior art, as recited in the instant specification. Applicants attention is directed to MPEP 2129, which states "a statement by an applicant in the specification or made during prosecution identifying the work of another as "prior art" is an admission **>which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988) and where the specification identifies work done by another as "prior art," the subject matter so identified is treated as admitted prior art. *In re Nomiya*, 509 F.2d 566, 571, 184 USPQ 607, 611 (CCPA 1975).

Applicant additionally argues Vandecruys teaches away from the instant invention and requires the presence of pregelatinized starch. While the examiner

concedes the necessity of pregelatinized starch, it is also submitted that Applicant is utilizing comprising language in the instant claims, thereby allowing for such a necessary inclusion. Vandecruys discloses a controlled release formulation comprising pregelatinized starch and one or more hydrophilic polymers. The instant claims do not exclude the pregelatinized starch.

Claims 1, 6-7, 9, 11-13, 17-19, 26-27 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al. (US Patent 6,395,300).

Straub discloses a drug formulation comprising a low aqueous solubility drug provided in a porous matrix (abstract). Phenytoin sodium is disclosed as a suitable drug (column 5, line 44) and the drug matrix is in the form of powder (column 13, lines 29-31). Additionally, the matrices also may contain hydrophilic excipient such as water soluble polymers or sugars, wetting agents including acacia gum, surfactants, and tonicity agents" (Column 3, lines 50-53). Straub further teaches, "the porous drug matrix can be processed into capsules for oral administration" (column 3, lines 4-6).

Straub discloses the hydrophilic polymers can include "hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyl-propylmethyl cellulose, and carboxymethyl cellulose" (column 8, lines 45-49).

Regarding Claim 6, "the porous drug matrix is at least 1-95% drug by weight" (column 3, lines 48-50).

Regarding Claim 7, Straub discloses, the amount of excipient in the drug matrix is less than 95% (column 8, lines 29-31). Straub defines excipient to include the hydrophilic polymers.

Regarding Claims 17-19, Straub discloses sugars such as "mannitol, dextrose and lactose" can be added to the drug matrix formulation (column 8, lines 58-65).

Regarding Claim 27, the selected drug is dissolved in an appropriate solvent; the drug solution is combined, typically under mixing conditions, with the pore forming agent or solution thereof. A solid pore forming agent can be added directly to the drug solution as solid particulates, preferably between about 100 nm and 10 um in size, to form a suspension of pore forming agent in the drug solution. Subsequently, further processing the resulting suspension, for example, using homogenization or sonication techniques known in the art, can reduce the solid pore forming agent particle size. Then, the solution, emulsion, or suspension is further processed to remove the drug solvent and the pore forming agent simultaneously or sequentially, using evaporation, spray drying, fluid bed drying, lyophilization, vacuum drying, or a combination of these techniques. The solvent and pore forming agents evaporate from the droplets into the drying gas to solidify the droplets, simultaneously forming pores throughout the solid. The solid (typically in a powder, particulate form) then is separated from the drying gas and collected" (column 11, line 47 to column 12, line 41). Since Straub discloses the dosage form can be in the form of capsules, it is the examiners position that capsules would be filled with the above resulting powder.

It is noted that Applicant is claiming a composition; therefore, the recitation of "wherein the powder blend has been screened through a mesh after blending but before filling in the capsules" is considered a process step, resulting in a product by process claim. The process step is therefore not given patentable weight when considering the

product claim. It is further noted that it is the position of the examiner that it would have been obvious to a person of ordinary skill in the art to filter or pass the powder through a mesh prior to filling the capsules in order to obtain a uniform particle size for the powder.

While it is noted that the prior art reference discloses phenytoin sodium among an extensive list of acceptable pharmaceutically active drugs, it is the position of the examiner that since it is specifically disclosed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected it from the disclosed list.

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant is again reminded the claims utilize "comprising" language allowing for the inclusion of any number of components. Applicant's arguments regarding the process steps are immaterial. Additionally, it is unclear what Applicants argument regarding the enhanced dissolution is. It is unclear is applicant is asserting enhanced dissolution is immediate release.

Claims 20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dilantin Physician Information Sheet in view of Vandecruys et al. (US Patent 6,667,060) and further in view of Sheth et al. (US Patent 4,588,589).

The combined teachings of the Dilantin Physician Information Sheet and Vandecruys are discussed above and applied in the same manner.

The use of microcrystalline cellulose and colloidal silicone dioxide are not disclosed.

Sheth discloses pharmaceutical dosage forms (abstract). Sheth further discloses compositions intended for oral use may be prepared according to methods known generally in the art. Such compositions may contain one or more agents selected from the group consisting of sweetening agents, flavoring agents, coloring agents and preserving agents in order to provide a pharmaceutically elegant and palatable preparation. Orally, they may be administered in tablets, lozenges, oily suspensions, dispersible powders or granules, or hard or soft capsules which contain the active ingredients in admixture with non-toxic pharmaceutically acceptable excipient. Excipients which may be, for example, inert diluents, such as lactose, microcrystalline cellulose, starch, dextrose and mannitol; and lubricants, glidants, and anti-adherants, such as for example, silicone fluids, microfine silicas and talc (column 3, lines 1-39).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one excipient in a specific class for another art recognize functional equivalent. The disclosure of Sheath leads one of ordinary skill in

the art to recognize microcrystalline cellulose is an art recognized equivalent of lactose and the same is true for silica and talc.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant did not provide any additional arguments regarding the inclusion of Sheth with Dilantin and Vandecruys. Therefore, the rejection is maintained for the reasons of record and the response to arguments presented above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615